Office of Biostatistics and Epidemiology/Division of Epidemiology
Periodic Safety Report Review Checklist

Completed by Reviewer

Product Name	Pfizer-BioNTech COVID-19 Vaccine
Manufacturer	Pfizer
STN #	IND19736.214
DCC Login ID #	980371
Submission Type	**PAER** ☐ **PSUR** ☑ **PBRER** ☐ **PADER** ☐
Submission Format	**ELECTRONIC** ☑ **PAPER** ☐
Reporting Period	**FROM** 01/01/2021 **TO** 01/31/2021
Date Received by FDA	02/16/2021
Date Routed to Reviewer	02/16/2021
Regulatory Information Specialist (RIS) - Name	Ramachandra Naik
Reviewer - Name	Kerry Welsh
Reviewer Signature (electronic signature)	Kerry J. Welsh -S Digitally signed by Kerry J. Welsh -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Kerry J. Welsh -S, 0.9.2342.19200300.100.1.1=2001896608 Date: 2021.03.03 10:18:10 -05'00'

COMMENTS

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1. Countries where the product is licensed or authorized for distribution:

   Not Reported ☐ US ☑ Worldwide ☑

2. Estimated number of doses distributed by reporting period/cumulative:

   Not Reported ☐ US (b) (4) doses cumulatively

   Not Applicable ☐ Worldwide 66,416,610 doses cumulatively

3. Does this report describe any actions taken by the manufacturer or other regulatory agency for this product (e.g. labeling changes)? Yes ☑ No ☐

4. Have there been any new safety issues identified by the reviewer in this PSUR? Yes ☑ No ☐

   If YES, please provide pertinent information below AND notify/discuss safety issues with the Team Lead and/or Branch Chief.

Q3. The EUA Fact Sheet for Healthcare Professionals was updated January 5, 2021 to indicate the use of 6 doses/vial was approved. Anaphylaxis was added as an adverse reaction to the EUA Fact Sheet on January 25, 2021.
Q4. The following safety signals were evaluated:
1) Hypersensitivity reactions, other than anaphylaxis, were evaluated and added to the label.
2) Pain in the extremity was evaluated. The sponsor plans to add this to the label.
3) Diarrhoea was evaluated. The sponsor plans to add this to the label.
4) Injection site pruritus was evaluated and determined not to be a risk.
5) Vomiting was evaluated. The sponsor plans to add this to the label.
6) Insomnia was evaluated and determined not to be a risk.

Conclusions:

☑ The contents of this PSUR/PAER do not indicate a need for further regulatory action.

☐ Please see the following comments and recommendations:

7) Deaths including in elderly or frail individuals was evaluated and determined not to be a risk.
8) Immune thrombocytopenia was evaluated and determined not to be a risk.
9) Overdose was evaluated. The sponsor determined no update to the label was needed.
10) Eye pain and swelling were evaluated and determined not to be risks.
11) Dizziness evaluation is ongoing.
12) Facial paralysis evaluation is ongoing.
13) Paresthesia evaluation is ongoing.
OVRR was notified of possible label changes in an email dated March 2, 2021.

Reference Documents (X:\DE\MEDICAL OFFICER\Guidance Documents):

1. E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs 1996
2. Addendum to E2C Safety Data Management: Periodic Safety Update Reports for Marketed Drugs 2004